

PREPARATION AND ASSEMBLY

After cleaning/disinfecting, the disassembled instruments should be reassembled and placed in their proper locations in the instrument cases.

CARE AND HANDLING OF INSTRUMENTS

- General.** Surgical instruments and instrument cases are susceptible to damage for a variety of reasons including prolonged use, misuse, rough or improper handling. Care must be taken to avoid compromising their exacting performance. To minimize damage and risk of injury, the following should be done:
 - Inspect the instrument case and instruments for damage upon receipt and after each use and cleaning. Incompletely cleaned instruments should be re-cleaned. Instruments in need of repair should be set aside for repair service or returned to Biomet (Instruments returned to Biomet or its distributors should be cleaned and sterilized prior to shipment. ANSI/AAMI ST35 Safe Handling and Biological Decontamination of Reusable Medical Devices in Health Care Facilities and in Nonclinical Settings provides guidelines for return, or contact Biomet or your distributor for further instruction).
 - Only use an instrument for its intended purpose.
 - When handling sharp instruments use extreme caution to avoid injury. Consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of direct instrument contact.**
- General Cleaning.** Clean instruments prior to initial sterilization and as soon as possible after use. Do not allow blood or debris to dry on the instruments. If cleaning must be delayed, place groups of instruments in a covered container with appropriate detergent or enzymatic solution to delay drying. Wash all instruments whether or not they were used or inadvertently came into contact with blood or saline solution.
- Ultrasonic Cleaners** can be used with hot water per manufacturer's recommended temperature (usually 90°-140°F or 32°-60°C) and specially formulated detergents. Follow manufacturer's recommendations for proper cleaning solution formulated specifically for ultrasonic cleaners. Be aware that loading patterns, instrument cassettes, water temperature, and other external factors may change the effectiveness of the equipment.
- Washer-Decontamination Equipment** will wash and decontaminate instruments. Complete removal of soil from crevices and serrations depends on instrument construction, exposure time, pressure of delivered solution, and pH of the detergent solution, and thus may require prior brushing. Be familiar with equipment manufacturers' use and operation instructions. Be aware that loading, detergent, water temperature, and other external factors may change the effectiveness of the equipment.

RESPONSIBILITIES OF THE USER

General. Health care personnel bear the ultimate responsibility for ensuring that any packaging method or material is suitable for use in sterilization processing and sterility maintenance.

Cleaning/Decontamination. The health care facility is responsible to insure that conditions essential to safe handling and decontamination can be achieved. ANSI/AAMI ST35 Safe Handling and Biological Decontamination of Reusable Medical Devices in Health Care Facilities and in Nonclinical Settings provides guidelines for design and personnel considerations, immediate handling of contaminated items and transportation, decontamination processes, servicing, repair, and process performance.

Sterility. Users should conduct testing in the health care facility to ensure that conditions essential to sterilization can be achieved and that specific configuration of the container contents is acceptable for the sterilization process and for the requirements at the point of use. ANSI/AAMI ST33 Guidelines for the Selection and Use of Reusable Rigid Container Systems for Ethylene Oxide Sterilization and Steam Sterilization in Health Care Facilities covers the selection and use of reusable rigid sterilization container systems. Guidelines are provided by this standard for cleaning and decontamination, preparation and assembly, sterilizer loading and unloading, matching the container system to the appropriate sterilization cycle, quality assurance, sterile storage, transport, and aseptic use.

WARNINGS AND PRECAUTIONS

Unless otherwise indicated, instrument sets are NOT sterile and must be thoroughly cleaned and sterilized prior to use.

Instruments should NOT be flash-autoclaved inside the instrument case. Flash-autoclaving of individual instruments should be avoided.

Recommendations for the Care and Handling Biomet® Surgical Instruments and Instrument Cases

DESCRIPTION

Biomet® instruments and instrument cases are generally composed of aluminum, stainless steel, and/or polymeric materials. The cases may be multi-layered with various inserts to hold surgical instrumentation in place during handling and storage. The inserts may consist of trays, holders, and silicone mats. The instrument cases are perforated to allow steam to penetrate these various materials and components. The instrument cases will allow sterilization of the contents to occur in a steam autoclave utilizing a sterilization and drying cycle that has been validated by the user for the equipment and procedures employed at the user facility. **Instrument cases do not provide a sterile barrier and must be used in conjunction with a sterilization wrap to maintain sterility.**

Materials

Aluminum
Stainless Steel
Polymeric Materials

DISCLAIMER

Biomet® instrument cases are intended to protect instrumentation and facilitate the sterilization process by allowing steam penetration and drying. Biomet has verified through laboratory testing that its instrument cases are suitable for the specific sterilization methods and cycles for which they have been tested. Health care personnel bear the ultimate responsibility for ensuring that any packaging method or material, including a reusable rigid container system, is suitable for use in sterilization processing and sterility maintenance in a particular health care facility. Testing should be conducted in the health care facility to ensure that conditions essential to sterilization can be achieved. Biomet does not accept responsibility or liability arising from a lack of cleanliness or sterility of any medical devices supplied by Biomet that should have been properly cleaned and/or sterilized by the end user prior to use.

CLEANING AND DECONTAMINATION

- Removal of Gross Contamination-**The effectiveness of subsequent decontamination processes depends on prior removal of gross soil as it may be impaired by dried or coagulated protein. Gross soil should be removed under running water using a mechanical aid such as a brush with rigid nylon bristles. Care should be taken to avoid splashing and generating aerosols by holding instruments below the surface of the water in a sink into which water is running and continuously draining. Instruments should not be held under a running tap, as this is likely to result in splashing. Operatives should wear protective equipment including gloves and goggles. Care should be taken to avoid penetrating or cutting injuries. Particular attention should be taken to remove all debris from all cannulations and obscure holes in the instruments.
- Disassembly-**The majority of surgical instruments and trial prostheses are constructed in such a way that they will not require disassembly. However, some of the more complex instruments are made of several components and these should be disassembled into their individual parts prior to decontamination. In most cases the method of disassembly is self-evident. Loosen and/or disassemble instruments with removable parts. Screws or bolts on some instruments can be loosened for cleaning but are self-retaining to prevent loss.
- Washing/Disinfecting-** It is recommended that the instruments, disassembled as required, be decontaminated using an automatic washer-disinfection unit utilizing thermal disinfection. This should preferably be of the ultrasonic or continuous tunnel process type. The cabinet type is an acceptable alternative if a continuous process machine is not available. (Typical initial cleaning temperature is at or below 95° F (35°C), followed by a hot water disinfectant rinse where the surface temperature of the instruments should reach a minimum temperature of 160°F (71°C) for a minimum of 3 minutes, 176°F (80°C) for a minimum of 1 minute, or 194°F (90°C) for 1 second.) Compatible detergents and rinse aids may be used as recommended by the manufacturer of the washer-disinfection unit. These detergents and/or rinse aids, however, should be of neutral or near neutral pH. Excessively acidic or alkaline solutions may corrode aluminum instruments or instrument cases.

Unwrapped instrument cases DO NOT maintain sterility.

A cannula set needs to be repaired and/or replaced when the fluid flow through the cannula around the scope is decreased.

STORAGE AND SHELF LIFE

Instrument cases that have been processed and wrapped to maintain sterility should be stored in a manner to avoid extremes in temperature and moisture. Care must be exercised in handling of wrapped cases to prevent damage to the sterile barrier. The health care facility should establish a shelf life for wrapped instrument cases based upon the type of sterile wrap used and the recommendations of the sterile wrap manufacturer. The user must be aware that maintenance of sterility is event-related and that the probability of occurrence of a contaminating event increases over time, with handling, and whether woven or non-woven materials, pouches, or container systems are used as the packaging method.

STERILITY

Unless otherwise indicated, instruments are NOT STERILE and must be thoroughly cleaned and sterilized prior to use.

Biomet® instruments can be steam autoclaved and repeated autoclaving will not adversely affect them, unless otherwise indicated in the labeling. If you have any problems when using Biomet® instruments or instrument cases, please bring this to Biomet's or Biomet's distributor's attention when you return them. (Instruments returned to Biomet or its distributors should be cleaned and sterilized prior to shipment. ANSI/AAMI ST35 Safe Handling and Biological Decontamination of Reusable Medical Devices in Health Care Facilities and in Nonclinical Settings provides guidelines for return or contact Biomet or your distributor for further instruction).

Unless supplied sterile, instruments must be thoroughly cleaned and sterilized prior to surgical use. Set forth below is a recommended minimum cycle for steam sterilization that has been validated by Biomet under laboratory conditions. Individual users must validate the cleaning and autoclaving procedures used on-site, including the on-site validation of the recommended minimum cycle parameters described below.

Surgical instruments may be autoclaved using a full cycle. Instruments that have been used in a surgical environment should be thoroughly cleaned prior to autoclaving. Use of ANSI/AAMI ST46 Steam Sterilization and Sterility Assurance in Health Care Facilities is recommended. The following cycle parameters are the minimum for instrument cases up to 25 lbs (11 kgs).

GRAVITY DISPLACEMENT STERILIZER (Full Cycle)

270° - 275° F (132° - 135° C) – Double or Single Wrapped or unwrapped
12 minutes exposure time - 8 minutes drying time.

PRE-VACUUMED STERILIZER (HI-VAC)

270° - 275° F (132° - 135° C) – Double or Single Wrapped or unwrapped
5 minutes exposure time - 8 minutes drying time.

Multi-Level Instrument Cases

In some instrument case designs, two or three individual instrument cases may be supplied with an outer transportation container. These instrument cases may be sterilized individually following the instructions above, or may be sterilized by placing the individual cases within the supplied transportation container. To sterilize two or three instrument cases within the supplied outer transportation container, the following sterilization cycle parameters are recommended. The following cycle parameters are the minimum for instrument cases up to 35 lbs. (16 kgs.).

PRE-VACUUMED STERILIZER (HI-VAC)

270° - 275° (132° - 135°C) – Double or Single Wrapped or unwrapped 10 minutes exposure time – 8 minutes drying time.

Since Biomet is not familiar with individual hospital handling procedures, cleaning methods, bioburden levels, and other conditions, Biomet assumes no responsibility for sterilization of product by a hospital even if the general above guidelines are followed.

CAUTION: Federal Law (USA) restricts this device to sale, distribution, or use by or on the order of a physician.

Comments regarding Biomet® devices or instruments can be directed to Attn: Regulatory Dept., Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, FAX: 574-372-3968.

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CLEANING AND STERILIZATION METHODS

Biomet® Rigid Instrument Cases - Suitable for Steam Autoclaving Aluminum, Stainless Steel, and Polymeric

Processing Steps	Suggested Method
Removal of gross contamination & disassembly	By hand submerged in water with continuous flow with mechanical aid (e.g. brush) wearing protective gloves & goggles Disassemble instruments into individual parts
Washing & Disinfecting	Automatic washer-disinfection unit utilizing thermal disinfection (ultrasonic or continuous tunnel process preferable) – Temperatures, cycles & disinfectant type used as instructed by manufacturer of washer-disinfection unit
Sterilization	Steam autoclave
Steam Autoclave Cycle Parameters*	<u>Gravity Displacement Sterilizer (Full Cycle)</u> 270°-275° F (132°-135° C) - Double or Single Wrapped or unwrapped 12 minutes exposure time – 8 minutes drying time <u>Pre-Vacuumed Sterilizer (HI-VAC)</u> 270°-275° F (132° - 135° C) - Double or Single Wrapped or unwrapped 5 minutes exposure time – 8 minutes drying time *Validated by Biomet under laboratory conditions; however, these cycles must be re-validated by the end-user to ensure that sterility can be achieved on site.
Precautions	When handling sharp instruments use extreme caution to avoid injury. Consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of direct instrument contact. Unless otherwise indicated, instrument sets are NOT Sterile and must be thoroughly cleaned and sterilized prior to use. Instruments should NOT be flash-autoclaved inside the instrument case. Flash-autoclaving of individual instruments should be avoided, whenever possible. Unwrapped instrument cases DO NOT maintain sterility.